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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,291	10/15/2003	Javier Castaneda	HAN-021 A	7101

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,291	CASTANEDA, JAVIER	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/28/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 13-16, 18-23, and 26-28* is/are rejected.

7)☒ Claim(s) *11,12,17,24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02-20-2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Claims 1-26 in the reply filed on 05/28/2004 is acknowledged. The traversal is on the ground(s) that all of the claims can be reasonably searched together. This is found persuasive and the requirement is cancelled. All 28 claims have been examined.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In claims 11 and 12, Applicant refers to a "shaft," while it appears that Applicant refers to this component in the specification as a "peg" 46. Applicant should use terminology consistent with the specification to clearly set forth what is being claimed.

3. Additionally, the "receiving means" of line 8 in claim 1 lacks antecedent basis in the specification so it is therefore unclear which component of the invention Applicant is referring.

4. Finally, in claim 28, the terminology seems to be inconsistent with the specification. The convex surface of plate (36) seems to correspond to the concave surface of "second portion" (106)—not the first portion as set forth in the claim. The language of the claim should be corrected so as to be consistent with the specification.

Claim Rejections - 35 USC § 112

5. Claims 3, 18, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Saying that the slots are "non-radial" is unclear. It is suggested that Applicant claim that the slots are not radially displaced from the holes, or use similar language. The terminology of claim 28 should be corrected to be clear (as described above).

6. Claim 15 recites the limitation "said arm" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-10, 13, and 14 are rejected under 35 U.S.C. 102(e) as being *clearly* anticipated by U.S. Patent No. 6,706,046 B2 to Orbay et al.

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed

in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claims 1, 6-8, and 10, Orbay discloses a jig assembly for use in implanting an orthopedic implant, as shown in Figure 10. First portion (78) has holes (84, 86) and second portion has holes (87, 88). Orbay discloses receiving means (80) capable of receiving a drill bit. Orbay discloses a drill guide (82). Screw (76) is a locking means capable of attaching and locking jig (78) to implant (10) when it is mated with hole (87) [Column 5, lines 59-61]. The inside of hole (26) is threaded to receive screw (28) [Column 3, lines 61-67].

Orbay discloses pegs (58, 60), which may be used as gauge means to measure the depth of holes drilled into the bone. Orbay explains that these pegs (58, 60) are inserted into the drilled holes in the bone [Column 6, lines 44-51]: Therefore, if the pegs protrude from the hole, the user knows that the hole is not deep enough. By comparing the depth the pegs (58, 60) go into the hole, the user can very accurately measure the depth of the hole (if the user measures the length of the pegs beforehand).

Alternatively, the drill bit used to drill the holes can be used as a gauge means.

Further, Applicant does not show any depth gauge, but *admits that scales for measuring the depth of a drilled hole are nothing new*, and are *well-known in the prior art* [specification, page 15, lines 19-22].

8. Regarding Claims 2 and 3, Orbay discloses slots (164) in screws (28) and identical screw (30) [see Fig. 6A; Column 4, line 19]. Each screw is screwed through

hole (84) or (86) respectively and therefore the respective slots (164) will be *in* (that is, inside of) longitudinally spaced holes (84 and 86) *in* the first portion of the jig. These slots are non-radial with the holes (84 and 86)—particularly when the jig is removed from contact with the patient at the end of the surgery.

9. Regarding Claim 4, receiving means (80) has a sleeve.

10. Regarding Claim 5, locking means (76) locks the jig parallel to implant (10).

11. Regarding Claim 9, the second portion has a concave undersurface, as is evident from Fig. 10.

12. Regarding Claims 13 and 14, Orbay discloses drill sleeve (76) having a smaller bore than hole (86) as is evident in Fig. 10.

13. Claims 1-8, 10, 13, 14, 16, 18-23, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,514,253 B1 to Yao. Regarding Claims 1 and 10, Yao discloses a jig assembly for use in implanting an orthopedic implant, as shown most clearly in Figures 2, 3, and 5. First portion (10/14/40/50/70) has holes (51, 63) and second portion has holes (22, 26). Yao discloses receiving means (37) capable of receiving a drill bit. Yao discloses a drill guide (36). Members (34, 30, 32) form a locking means capable of attaching and locking jig to implant (intramedullary nail extending from member 32 in Fig. 7) when they are mated [shown in locked position in Fig. 7].

Yao shows drills with corresponding bits as dashed lines in Figure 7 [Column 1, lines 62-63]. As the user is drilling holes in the bone, the user can compare the

proximal end of the drill bit/drill to the upper surface of member 14 in order to gauge the depth that the drill bit is moving distally as it is extended. These components in sum, therefore, can be called "gauge means" because they are capable of being used by the surgeon to mark the depth that the drill bit penetrates relative to the skin or bone of the patient.

Further, Applicant does not show any depth gauge, but *admits that scales for measuring the depth of a drilled hole are nothing new*, and are *well-known in the prior art* [specification, page 15, lines 19-22].

First portion (10/14/40/50/70) is parallel and vertically displaced relative to the implant. Second portion (11, 20) is seated on the implant.

14. Regarding Claims 2, 3, and 16, Yao discloses longitudinally spaced holes (42) [see exploded view: Figure 1] in the first portion of the jig, each of the holes having a slot. With reference to component (40) of Figure 1, it is evident that there is a rectangular slot, which cuts through the center of component (40), forming a hole in its center—cutting through hole (42) [which extends through the entire length of component (40)]. The slots are non-radial, relative to the holes; i.e. each slot extends in different directions from the hole.

15. Regarding Claim 4, receiving means (37) includes a sleeve—a cylinder [Fig. 1].

16. Regarding Claim 5, component (35) locks onto the intramedullary implant [Fig. 5].

17. Regarding Claim 6, holes (22 and 26) are spaced apart longitudinally along the axis of member (20).

18. Regarding Claim 7, hole (12) is laterally displaced from hole (26). That is, hole (12) is in the central axis of the second portion, whereas hole (26) extends all the way through (laterally) the second portion.

19. Regarding Claim 8, hole 26 is bounded along its circumference.

20. Regarding Claim 13, Yao discloses a drill sleeve (36) [there are two drill sleeves (36) shown in the figures] including a tube with a longitudinal passage. Yao discloses a bearing (77), which bores into the axis of the sleeve (36). Bridge (70) is laterally displaced from the sleeve and couples the sleeve and bearing.

21. Regarding Claim 14, the passage extending through member (36) has a smaller diameter than bore hole (76).

22. Regarding Claim 18, the slots are non-radial relative to the holes.

23. Regarding Claims 19 and 20, Yao's first portion has many openings (22), which are symmetrical and "lateral". It is unclear what Applicant means by "lateral" as the holes in his second portion seem to be longitudinally aligned. Regarding Claim 20, hole (26) is distal to holes (22).

24. Regarding Claims 21 and 22, Yao discloses a jig assembly including a rigid member (10). The whole jig assembly, including rigid member (10) is removably couplable from the implant [compare exploded view Figure 1 with Figure 5 in which the jig is connected to the implant]. From exploded view Figure 1, it is evident that member (10) has opening (12). Yao discloses member (30), which has a distal tubular portion and acts as a guide of intramedullary implant [compare Fig. 1 with Fig. 4]. Its length does not extend above the upper surface of rigid member (10).

Proximal tubular portion (21) is movable within opening (12). Yao further discloses drill bit (as shown in dashed lines in Fig. 7). The distal tip of the drill bit has a tip, which has a relatively small diameter compared with the diameter of most of the length of the drill bit. The drill bit is capable of performing the mentioned functions.

25. Regarding Claim 23, portion (22) of the guide (21/22/30) is a bridge portion, which separates portion (21) from portion (30). It is offset relative to the portions (21) and (32).

26. Regarding Claim 26, friction between the inner surface of hole (12) and tubular member (21) will prevent the two from rotating relative to each other.

27. Claim 27 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,692,496 B1 to Wardlaw. Wardlaw discloses implant (2) [Fig. 1(c)] with two portions that are longitudinally and vertically displaced from each other: they are at an angle relative to each other and therefore one is vertically above the other and portions of it are longitudinally displaced from the other portion. Wardlaw's jig (21) has member (21) having two portions at an angle relative to each other [see Fig. 7]. Each portion has holes therein: the holes in one portion are evident in Fig. 7, and the holes in the other portion are evident in Fig. 11. The jig is coupled to the implant at (22) in Fig. 4. One part of the jig is parallel to one part of the implant and the other part of the jig (at an angle) is connected to/seated on the proximal end of implant (2) at (22) [Fig. 5].

Allowable Subject Matter

28. Claims 11, 12, 17, 24, and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,746,453 to Delogeet et al.

U.S. Patent No. 5,658,283 to Huebner

Publication No. 2003/0055428 A1 to Swanson

U.S. Patent No. 6,579,293 B1 to Chandran

U.S. Patent No. 5,928,234 to Manspeizer

Publication No. 2003/0216742 to Wetzler et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
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September 2, 2004

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER